DATA EVALUATION RECORD
§ 71-4 (a) -- AVIAN REPRODUCTION TEST

1. **CHEMICAL:** MANCOZEB PC Code No.: 014504

2. **TEST MATERIAL:** Mancozeb technical Purity: 86.2-88.5%

3. **CITATION: Mancozeb: Reproduction in the Bobwhite Quail**

Author: A.J. Johnson
Title: see citation
Study Completion Date: 3/12/93
Laboratory: Huntingdon Life Sciences Ltd. (England)
Sponsor: Mancozeb Task Force
Laboratory Report ID: PWT 99/920944
MRID No.: 442380-01
DP Barcode: D234630

4. **REVIEWED BY:** N.E. Federoff, Wildlife Biologist, EEB, EFED

Signature: [signature] **Date:** 4/4/97

5. **APPROVED BY:** Ann Stavola, Head of Section (5), EEB, EFED

Signature: Ann Stavola **Date:** 4/9/97

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: (Colinus virginianus)
Age of Test Organisms at Test Initiation: approx. 26 weeks
Definitive Study Duration: 22 weeks

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an avian reproduction study.

Results Synopsis
Most sensitive endpoints: Weight of 14-day survivors

NOEC: 300 ppm ai LOEC: 1000 ppm ai

8. **ADEQUACY OF THE STUDY**

A. **Classification:** Core
B. **Rationale:** Fulfills guideline requirements
C. **Repairability:** N/A

9. **GUIDELINE DEVIATIONS**

1.

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10. **SUBMISSION PURPOSE:** To fulfill requirements for reregistration.

11. **MATERIALS AND METHODS**

A. Test Organisms

Guideline Criteria	Reported Information
Species A wild waterfowl species, preferably the mallard (*Anas platyrhynchos*), or an upland game species, preferably the northern bobwhite (*Colinus virginianus*)	Northern Bobwhite (*Colinus virginianus*)
Age at beginning of test Birds should be approaching their first breeding season.	26 weeks old, approaching 1st breeding season
Supplier All birds should be from the same source.	Yes; from Wise, Monkfield, Bourn, and Cambridgeshire
Were birds pen-reared?	Not reported but it is assumed since they were obtained from a breeder
Were birds phenotypically indistinguishable from wild birds?	Not reported
Health observation period 2 to 6 weeks.	4 weeks
Were birds healthy and without excessive mortality prior to the test?	5 birds died or were sacrificed prior to treatment and were replaced

B. Test System

Guideline Criteria	Reported Information
Were pens for adult birds of adequate size and designed to conform to good husbandry practices?	Adults were housed indoors in batteries of pens .31 x .39 x .24 m constructed of polythene -coated steel wire with sloping floors.

Guideline Criteria	Reported Information
Were pens for chicks of adequate size and designed to conform to good husbandry practices?	Chicks were housed in wooden box floor pens in a room separate from the adults.
Where pens constructed of a nonbinding material such as galvanized or stainless steel?	Yes for adults; No for chicks
Was adequate ventilation provided?	Reported as suitable environmental conditions for the species.
Temperature Approx. 21°C (70°F)	Ave Temp: 17-20 C
Relative humidity Approx. 55%	Average relative humidity: 69%
Lighting First 8 weeks: 7 h per day. Thereafter: 16-17 h per day. At least 6 footcandles at bird level.	First 7 weeks: 7 h per day. Thereafter: 16 h per day. Mean illumination= 42.5 lux Randomization of groups was designed to take into account variations in light intensity between the tiers of the batteries.
Diet A commercial breeder feed (or its equivalent) that is appropriate for the test species.	Adults: Quail layer diet manufactured by Special Diet Services, Essex, England containing 25% protein was fed during duration of testing. Hatchlings: Fed HRC chick meal made by Parker Bros., Suffolk, England.
Preparation of test diet A premixed containing the test substance should be mechanically mixed with basal diet. If an evaporative vehicle is used, it must be completely evaporated prior to feeding.	A premix was prepared by blending the amount of test substance with the diet. Diets were prepared weekly.
Was the premix stored under conditions which maintain stability?	Yes, stored at -20 C

Guideline Criteria	Reported Information
Was the diet analyzed to verify homogeneity and stability of the test substance?	Yes
Replenishment of feed	Pens were equiped with feeders. Feed replaced 2x weekly.

C. Test Design

Guideline Criteria	Reported Information
Nominal concentrations At least two concentrations other than the control are required; three or more are strongly recommended. The highest test concentrations should show a significant effect or be at or above the maximum field residue level.	Nominal concentrations: Control, 50, 300, and 1000 ppm
Control Vehicle control.	Untreated basal diet.
Vehicle Corn oil or other appropriate vehicle.	No vehicle was needed.
Vehicle amount (% of diet by weight) Not more than 2%.	N/A
Number of birds per pen One male and 1 female per pen is strongly recommended. For quail, 1 male and 2 females may be acceptable. For ducks, 2 males and 5 females may be acceptable.	1 male and 1 female per pen.

Guideline Criteria	Reported Information
Number of pens per group At least 5 replicate pens are required for mallards housed in groups of 7. For other arrangements, at least 12 pens are required, but considerably more may be needed if birds are kept in pairs.	24 pairs per group: 1 control group, 50 ppm group, 300 ppm group, and 1000 ppm group. 192 birds total (96M;96F).
Pre-laying exposure duration At least 10 weeks prior to the onset of egg-laying.	10 weeks
Exposure duration with egg-laying At least 10 weeks.	12 weeks
Withdrawal period If reduced reproduction is evident, a withdrawal period of up to 3 weeks may be added to the test phase.	N/A

D. Egg Collection and Incubation

Guideline Criteria	Reported Information
Were eggs collected daily?	Yes
Egg storage temperature Approximately 16°C (61°F)	mean temp= 16 C
Egg storage humidity Approximately 65%	Not reported
Were eggs set weekly?	Yes
Were eggs candled for cracks prior to being set for incubation on Day 0?	Yes-weekly
Candling for fertility Quail: approx. Day 11 Ducks: approx. Day 14	Eggs were candled on Day 11 and day 18
Transfer of eggs to hatcher Bobwhite: Day 21 Mallard: Day 23	Eggs were transferred on Day 21

Guideline Criteria	Reported Information
Hatching temperature 39°C (102°F) is recommended	37.5 C Ave
Hatching humidity 70% is recommended	Not reported, incubator had 55% relative humidity.
Day after egg set that chicks were removed and counted Bobwhite: Day 24 Mallard: Day 27	Chicks were removed and counted after day 21.

E. Eggshell Thickness Measurement

Guideline Criteria	Reported Information
Collection Schedule At least once every two weeks (Week 1, 3, 5, 7 and 9).	Eggs were collected daily.
Were shells opened, washed, and air dry for at least 48 hours before measuring?	Yes
Measurement 3-4 measurements per eggs to the nearest 0.01 mm.	4 measurements per egg to the nearest 0.01 mm using a micrometer.

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Did diet analysis verify the concentrations of test material?	Yes test 0 50 300 1000 mean diet 0 52.6 302.6 1001 (concentrations listed as ppm) A spectrophotometric method was used (CS_2 Evoloution)
Did diet analysis show that the test substance was stable and homogeneous?	Yes

Guideline Criteria	Reported Information
Were body weights of adults reported for test initiation and biweekly up to week 8 or the onset of egg laying?	Body weights reported for days 1, 71, and 155 of the study.
Was average food consumption of adults reported at least biweekly?	Yes, calculated biweekly.
Reproductive Endpoints The following endpoints should be reported: ● Eggs laid ● Eggs cracked ● Eggs set ● Viable embryos ● Live 3-week embryos ● Normal hatchlings ● 14-day-old survivors ● Weights of 14-day-old survivors ● Egg shell thickness ● Total food consumption ● Initial and final body weights, by sex	The following endpoints were measured: *All eggs laid were reported. *All eggs cracked were noted. *All eggs set were reported. *All viable embryos reported. *Live 3 week embryos reported. *Normal hatchlings reported. *All 14-day survivors noted. *All weights of 14-day suvivors were recorded. *All egg shell thickness noted *TFC reported for adults. *Adult weights recorded.
Were data reported by pen for all endpoints?	Yes

Significant Results: Reported statistical analysis conducted by Huntingdon Life Sciences found these significant results: At 1000 ppm, slight reductions were observed in fertility and in the proportions of normal hatchlings of fertile eggs and of live 3-week embryos. The proportion of normal hatchlings of eggs set was reduced ($P<0.05$) as was the proportions of 14-day survivors of eggs set and of eggs laid. The number of 14-day survivors per female was also slightly reduced. This reduction was reported as a cumulative effect resulting from the combined reductions in fertility and hatchability, and is considered likely to be of biological importance. No treatment level effects were apparent at the 300 ppm test concentration. Therefore, 300 ppm is considered to be the NOEL.

13. VERIFIED STATISTICAL RESULTS

Means of Endpoints and SD (# below the mean)

Endpoint	Control	50 ppm	300 ppm	1000 ppm
Eggs laid (EL)	53.46 27.01	55.92 22.57	56.54 21.94	53.21 25.80
Eggs cracked (EC)	2.75 3.43	2.25 3.47	3.25 4.59	2.17 2.76
Eggs set (ES)	47.38 23.65	49.92 20.52	47.04 22.45	47.46 22.64
Viable embryos (VE)	45.57 21.13	44.54 21.41	43.96 23.92	39.00 22.67
Live 3-wk embryos (LE)	44.48 20.58	42.96 20.41	42.25 24.08	37.08 21.49
Normal hatchlings (NH)	38.25 20.42	37.21 17.90	37.08 22.62	29.96 17.30
14-day-old survivors (HS)	34.17 18.48	33.75 17.24	33.33 21.58	26.50 16.49
Egg shell thickness (THICK)	0.21 0.01	0.22 0.02	0.21 0.01	0.21 0.013
Hatchling weight (HATWT)	6.57 0.45	6.48 0.51	6.67 0.41	6.40 0.59
14-day-old survivor weight (SURVWT)	23.60 2.03	23.49 1.35	23.68 2.03	22.08 1.74
Mean food consumption (FOOD)	17.98 1.89	18.42 1.19	18.63 1.96	18.75 1.59
Final weight of males (POSTM)	194.77 14.30	192.65 14.50	196.14 16.27	189.35 12.09
Final weight of females (POSTF)	216.73 19.24	211.14 25.09	219.27 20.94	206.57 31.59

Statistically Significant Endpoints

Endpoint	Statistical Method	Levels at which Effect Was Observed
14 day surv wt	LSM & Tukey's (HSD) and Dunnett's	1000 ppm

14. REVIEWER'S COMMENTS: Statistically significant endpoints found using the Least Squared Means test (LSM) were reported above but were not used as being significant due to the inflated experimentwise error caused by (LSM) comparisons.

EEB FILE

DP Barcode : D234630
PC Code No : 014504
EEB Out : APR 12 1997

To: Walter Waldrop
Product Manager 71
Reregistration Division

From: Dan Rieder, Acting Chief
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # :0643
Chemical Name :Mancozeb
Type Product :Fungicide
Product Name :Technical
Company Name :Mancozeb Task Force
Purpose :Review Avian Reproduction Study
Action Code :627 Core Data Date Due :6/24/97
Reviewer :N.E. Federoff (Wildlife Biologist)

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)	442380-01		72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(C)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur